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Policies and Procedures

Title: Institutional Animal Care and Use Committee

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P&P 635.1 “Humane Animal Care and Use” dated 8/29/90

Distribution: ARS Headquarters, Areas, and Locations

This Directive states policy, responsibilities, committee membership, and committee procedures, including reporting requirements, for ARS Institutional Animal Care and Use Committees. This policy applies to all ARS research and testing projects that involve live animals including: (a) ARS locations, regardless of funding or physical resources, and (b) all ARS research projects located at non-ARS locations using ARS personnel, facilities, or funding.

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Purpose

The U.S. Department of Agriculture (USDA) Agricultural Research Service (ARS) leadership recognizes the significant scientific advances and benefits to the health and well-being of animals and the public that have been achieved through the conscientious use of live animals in research, testing, and teaching, and is committed to ensuring the highest standards of animal care and use, as defined through the Animal Welfare Act Regulations (AWAR) and other relevant Federal guidelines and policies. This Policy and Procedure (P&P) describes the core principles that serve as a foundation for the compassionate care and ethical oversight of all animals that are used in ARS research activities.

Background

The use of animals for research purposes imposes moral, scientific, and legal obligations on the sponsoring institution to ensure that its program of care and use is humane and based on our best scientific understanding of the biological and behavioral needs of the animals. ARS leadership recognizes the unique challenges and responsibilities that accompany agricultural-based research, and is steadfastly committed to the development and implementation of effective strategies that will further improve the quality of care for all animals that are used in support of ARS research efforts.

Congress enacted the Animal Welfare Act (AWA) in 1966. It remains the only Federal statute that regulates the treatment of animals used in research, testing, and teaching in the United States, and is widely recognized as the definitive standard for the basic care and treatment of regulated species. These include live, warm-blooded vertebrate species used in teaching, testing, experiments, or research protocols. Invertebrates, cold-blooded vertebrates, birds, domestic rats (*Rattus* species) and mice (*Mus* species) bred specifically for research, and farm animals used or intended to be used for food and fiber are exempt, in addition to any animals that are used for improving breeding, management, production efficiency, or animal nutrition or for improving the quality of food and fiber. USDA Animal and Plant Health Inspection Service (APHIS) Animal Care is the administrative unit that is charged with enforcing the AWA and corresponding AWAR. Federal institutions are not required to register and are not routinely inspected by APHIS, but each Federal agency is responsible for complying with all USDA standards of animal care. ARS locations performing research with regulated species must comply with these requirements.

In addition, ARS locations receiving funds from the Public Health Service (PHS) to conduct research with animals must also comply with PHS Policy. PHS Policy implements the U.S. Government Principles, which were developed by the Interagency Research Animal Committee

and adopted by the Office of Science and Technology Policy in 1985. This policy serves as the foundation for humane care and use of laboratory animals in this country. Funded institutions are expected to use the National Research Council publication titled “*Guide for the Care and Use of Laboratory Animals*” (*Guide*) as a basis for developing and implementing an Animal Care and Use Program (ACUP) that is consistent with PHS Policy. Compliance with the AWAR, as applicable, is also an absolute requirement of PHS Policy.

Most ARS locations conduct research with livestock, poultry, and/or aquatic species, which is focused exclusively on agricultural applications. In these situations, ARS endorses the animal care philosophies and principles that are articulated in the most recent edition of the publication titled “*Guide for the Care and Use of Agricultural Animals in Research and Teaching*” (*Ag Guide*) to ensure the appropriate care, treatment, and use of agricultural species in research, and the Canadian Council on Animal Care “*Guidelines on: the care and use of fish in research, teaching, and testing*” (*CCAC Guidelines*) to ensure the appropriate care, treatment, and use of aquatic species in research.

In keeping with these standards, ARS recognizes that a robust local oversight system is integral to success, and has mandated that an appropriately qualified and functioning Institutional Animal Care and Use Committee (IACUC) be established to guide these efforts. This P&P articulates the roles, responsibilities and designated functions of IACUCs that have direct or delegated oversight authority for ARS research involving animals.

Policy

In accordance with the laws, regulations, and policies that pertain to research involving live animals, an appropriately constituted and qualified IACUC must be designated for every ARS location that conducts research with animals. This can be accomplished by establishing a location-based IACUC that is administered by ARS employees, or by establishing a formal agreement for the use of a committee that is administered by an external research partner. The IACUC of record for each ARS location must be granted absolute authority to ensure all animals are treated humanely and receive care that is consistent with prevailing standards for the species and the type of research that is conducted.

Responsibilities

1. The ARS Administrator will:

- a) Through the Office of National Programs (ONP), establish policies, guidance, and internal and external assessment procedures to ensure all ARS research activities involving live animals adhere to the humane principles and recognized standards of animal care and use

articulated in the AWAR, PHS Policy, *Ag Guide*, *CCAC Guidelines*, and/or other applicable regulations, guidelines, and policies.

- b) Ensure adequate resources (e.g., staff, funding, training, equipment, etc.) are dedicated to the development, implementation, management, and operation of a comprehensive ACUP at every ARS location that conducts research involving animals.
- c) Promote the development or procurement of systems (e.g., IACUC tracking and approval software, electronic document management systems, etc.), tools, and services that support the operation and management of comprehensive and effective ACUPs.
- d) Ensure ARS research programs and facilities that use animals in research, testing, or teaching are operated and managed in a manner that promotes and supports a viable ACUP and conforms to ARS's commitment to conscientious animal care and use.
- e) Ensure ACUPs are reviewed on a routine basis and that the criteria for these reviews are based on established guidelines, recognized consensus standards, and scientific data that are generated in support of specific Agency goals, objectives, and/or criteria directed toward improving the standards of animal care and use. Furthermore, the results of these reviews will be documented and used to drive future quality initiatives.
- f) Appoint the Agency Animal Welfare Ombudsman and support Agency-wide requirements to establish policies that protect any individual who reports an animal care concern from retribution or retaliation for their actions (i.e., Whistleblower Protection).

2. ARS Associate Administrator for National Programs will:

- a) Support and promote the responsible conduct of science that is sponsored through the ONP and promote/reinforce the need for project design to be in accordance with ARS policies and relevant regulations and policies related to the humane care and use of animals.
- b) Ensure all Project Plans utilizing research animals are properly planned, coded, and/or marked for review and evaluation in accordance with this ARS Policy.
- c) Support Agency-wide requirements to establish policies that protect any individual who reports an animal care concern from retribution or retaliation for their actions (i.e., Whistleblower Protection).

3. ARS Associate Administrator for Research Operations will:

- a) Provide oversight, accountability for compliance and guidance to Area Directors and Deputy Administrators for Administrative and Financial Management to ensure resources are available for the operation, management, and evaluation of comprehensive ACUPs, as appropriate and applicable within Administrative and Financial Management.
- b) Ensure reporting systems are in place.
- c) Support Agency-wide requirements to establish policies that protect any individual who reports an animal care concern from retribution or retaliation for their actions (i.e., Whistleblower Protection).

- d) As required, serve as the ARS liaison with APHIS Animal Care to provide a formal means for communication and coordination between the two agencies.

4. ARS Deputy Administrator for Animal Production and Protection will:

- a) Provide management support, subject matter expertise, resources, accountability, and oversight to the Agency ACUP.
- b) Chair the Animal Care and Use Leadership Steering Committee for ARS and provide feedback to the Animal Care and Use Officer and ARS Animal Welfare Task Force relative to quality initiatives and special assignments intended to improve the care and treatment of animals used in ARS research.
- c) Through designated subject matter experts, provide oversight and support for compliance of ARS IACUC activities and support for locations to adhere to applicable regulations and policies that pertain to animal welfare as required for scientific/research activities.
- d) Support Agency-wide requirements to establish policies that protect any individual who reports an animal care concern from retribution or retaliation for their actions (i.e., Whistleblower Protection).

5. ARS Deputy Administrator, Office of National Programs (other) will:

- a) Support and provide oversight as appropriate for all research involving the use of research animals to ensure these activities are planned and adequately reviewed and comply with the applicable regulatory standards, industry guidelines, best practices, and ARS policies.
- b) Promote and support the incorporation of ARS animal welfare principles into the planning phase of the project development.
- c) Support Agency-wide requirements to establish policies that protect any individual who reports an animal care concern from retribution or retaliation for their actions (i.e., Whistleblower Protection).

6. ARS National Program Leaders will:

- a) Support and promote the responsible conduct of science that is sponsored through the National Research Programs and promote/reinforce the need for project design to be in accordance with ARS policies and relevant regulations and policies related to the humane care and use of animals.
- b) Support Agency-wide requirements to establish policies that protect any individual who reports an animal care concern from retribution or retaliation for their actions (i.e., Whistleblower Protection).

7. ARS Animal Care and Use Officer will:

- a) Administer the Agency ACUP and advise senior leadership on applicable regulations and standards, changes to regulations, status of the ACUPs within ARS, and instances of non-compliance and unexpected incidents involving the use of animals in research.
- b) Advise on practices and procedures needed to support and improve the humane care and use of animals in ARS research activities.
- c) Chair and coordinate the efforts of the ARS Animal Welfare Task Force.
- d) Coordinate annual certification procedures intended to verify the effectiveness of local oversight systems at all ARS locations that conduct research involving animals.
- e) Coordinate centralized reporting of significant noncompliance and/or unexpected adverse events involving research animals at all ARS locations, and implement Agency-wide strategies to address cross-cutting issues or trends.
- f) Coordinate announced and unannounced internal audits of ARS research locations, IACUCs, and/or individual research projects to ensure compliance with ARS policy and applicable regulations and guidelines.
- g) Coordinate and ensure annual reporting and certification of all ARS IACUCs to the ONP and external oversight agencies, as required, and review, approve, and forward all outgoing incident and violation reporting from ARS IACUCs through the ONP to the appropriate external authority(ies).
- h) Appoint *Ad Hoc* working groups and/or committees, as needed and appropriate.
- i) Facilitate the incorporation of best practices relevant to the care and use of animals in research into ARS facility operations and research projects, as needed.
- j) Represent ARS on USDA Animal Care and Use Committees or Working Groups and other interagency working groups, as appropriate and assigned.
- k) Support Agency-wide requirements to establish policies that protect any individual who reports an animal care concern from retribution or retaliation for their actions (i.e., Whistleblower Protection).
- l) Coordinate with each location's IACUC to develop site-specific, long-range training programs that will include periodic refresher training and updates on new regulatory requirements, policies, and best practices.
- m) Schedule and coordinate an annual review and update of this P&P to ensure that it includes advances in best practices, science, and technology.

8. ARS Animal Welfare Ombudsman will:

- a) Work in collaboration with ARS locations by providing an alternative option for individuals or groups to report concerns related to the care and/or welfare of animals owned by ARS or used in ARS research activities when local oversight options have been exhausted.
- b) Report directly to the ARS Administrator, and serve as an impartial and independent intermediary in the investigation and satisfactory resolution of animal care concerns involving ARS research, staff, and/or locations.

- c) Monitor communications received through an email portal that has been specifically established to receive animal care and use reports intended for the Ombudsman (animalwellbeing@ars.usda.gov).
- d) Attempt to preserve sensitive information and the confidentiality of person(s) who raised concerns, even though this information may be released during the ensuing investigation and result in the identity of the individual(s) associated with the report and/or incident to be disclosed.
- e) Support measures to ensure that those who report concerns are protected and do not face retaliation and/or reprisal for raising these issues.
- f) Work with the location IACUC and Animal Care and Use Officer to ensure that all concerns are investigated in a timely manner and, when needed, that effective corrective actions are promptly implemented to address any potential deficiencies in the care, treatment, and/or use of animals owned, managed, and/or used by ARS.
- g) Submit quarterly reports to the ARS Administrator that summarizes the number of concerns received, the general nature of these concerns, investigation results and analysis, subsequent actions implemented to address the concern(s), and potential trends that may require a broader Agency response, which includes recommendations for strategies that will further enhance the welfare of ARS animals.

9. ARS Area Directors will:

- a) Serve as members of the ARS Animal Care and Use Leadership Steering Committee, and actively participate in the development and implementation of this ARS P&P for the responsible care and use of animals in ARS research.
- b) Ensure the P&P is disseminated to all ARS locations within their respective jurisdictions and that the associated requirements are implemented within proposed timeframes.
- c) Manage available staff and resources to provide the level of support that is needed to establish, maintain, and support an effective local oversight system for animals used in research at all locations within their respective Areas, as necessary.
- d) Ensure that a high-ranking supervisor or executive, who has adequate authority and resources to ensure compliance with ARS requirements, is designated in writing to serve as the Institutional Official (IO) for animal research at every ARS location that conducts research with animals.
- e) Ensure that all research projects involving animals at either an ARS location (regardless of source of funds) or at another location authorized to use ARS resources is reviewed by an IACUC.
- f) Ensure compliance with ARS policies and applicable federal regulations and guidelines that pertain to animal welfare as required for scientific/research activities.
- g) Ensure that noncompliance with ARS Policy and/or applicable federal regulations and policies is appropriately reported to the location IACUC and ARS Animal Care and Use Officer, documented, and resolved or corrected in a timely manner.

- h) Assume an active role in the investigation and mitigation of animal welfare concerns that have been identified and cannot be satisfactorily resolved at the local level, including the implementation of disciplinary actions when warranted.
- i) Coordinate data collection within their respective jurisdictions, and ensure timely reporting of this information to the appropriate authorities.
- j) Support Agency-wide requirements to establish policies that protect any individual who reports an animal care concern from retribution or retaliation for their actions (i.e., Whistleblower Protection).

10. ARS Location Senior Management Official will:

- a) Serve as the IO for the location's ACUP, if appointed by the Area Director.
- b) Develop, implement, support, and/or provide oversight for a location ACUP that conforms with and supports Agency policies and Area guidance for the welfare of animals used in ARS research activities.
- c) Provide resources for operation, training, and establishment of a local IACUC or execute a formal agreement to obtain the services of an externally administered and appropriately constituted IACUC for the oversight of ARS research activities involving live animals.
- d) Ensure that formal, written inter-institutional agreements are established with research partners that clarify the specific animal care and use oversight responsibilities of each party to the agreement, including delegation of the oversight of ARS research involving animals to another organization, or assuming oversight for collaborative research involving animals that are owned by ARS, another institution, industry, and/or private individuals.
- e) Establish a process to ensure that all research projects and experiments using animals receive IACUC review and approval in accordance with this P&P.
- f) Formally appoint a qualified ARS employee, or make arrangements with a veterinary consultant (DVM, VMD, or equivalent) who has appropriate training and experience with the species that are used in the location's research activities, to serve as the Attending Veterinarian (AV) for the location's ACUP.
- g) Ensure there is adequate supervision of guest researchers, visiting scientists, students, and other individuals who participate in ARS research activities involving animals, and that these individuals adhere to this P&P when working with ARS-owned or leased animals.
- h) Ensure programs and facilities they oversee, which are owned (or leased) and managed by ARS and that have established an IACUC for oversight of animals used in ARS research, establish a registration with USDA-APHIS Animal Care that includes all sites where ARS research is conducted, regardless of the species that is used.
- i) Submit annual reports and certifications to the ARS ONP, and other external oversight and/or accrediting entities, as required.
- j) Host and facilitate site visits and inspections conducted by oversight and/or accrediting entities to evaluate the location's ACUP.

- k) Ensure the satisfactory resolution of any deficiencies that are identified during external site visits or inspections and/or through IACUC semi-annual program reviews and facility inspections.
- l) Encourage employees to report any concerns related to the care and treatment of animals used in ARS research to the location's IACUC and other appropriate authorities, as needed.
- m) Support Agency-wide requirements to establish policies that protect any individual who reports an animal care concern from retribution or retaliation for their actions (i.e., Whistleblower Protection).

11. ARS Institutional Officials (IO) will:

- a) Ensure the formal appointment of members that are needed to establish a properly constituted IACUC, including individuals who are qualified by experience and/or training to evaluate the location's ACUP and research proposals involving animals.
- b) Ensure that the location's IACUC has at least 5 members that include: (1) the AV; (2) a scientist who has experience in the species and agricultural research activities that are relevant to the location; (3) an animal, dairy, poultry, or aquaculture scientist who has training and experience in the management of these animals; (4) a person whose primary concerns are in a nonscientific area and who has no prior animal research experience; and (5) a person who is not affiliated with the institution in any way and who has no family members who are employed by the institution. In some cases, one individual may be qualified to fulfill more than one of the required roles concurrently (i.e., nonscientist and nonaffiliated roles). However, a minimum of 5 voting members is still required.
- c) Appoint one of the IACUC members, other than the AV, to serve as the IACUC Chair.
- d) Ensure locations that receive funding from the Public Health Service (PHS) adhere to PHS Policy IACUC membership requirements, which also requires a minimum of 5 members that include a qualified veterinarian, a nonaffiliated member, a scientist experienced in animal research, and a nonscientist.
- e) Formally request a waiver from the Animal Care and Use Officer to establish an IACUC that deviates from these standards, such as a committee with 3 members as required by the AWAR, when the number of staff and/or physical location of the facility interfere with the recruitment of 5 qualified individuals to serve on the IACUC. An appropriate written justification must be provided for the waiver request, and each request will be considered on a case-by-case basis.
- f) Appoint the members in writing for terms not to exceed 3 years. The term of appointment can be open or indefinite, if serving as an IACUC member is a requirement of that individual's official position (e.g., the AV). Members may be reappointed to concurrent terms without an interruption in service, although rotation of members is strongly encouraged whenever possible.
- g) Assign direct or delegated authority and responsibility to the AV for the location's ACUP, animal facilities, and activities involving animals, including the ability to ensure the

provision of adequate and timely veterinary care that is consistent with the conditions of IACUC approval and to oversee the adequacy of other aspects of the husbandry and treatment of animals.

- h) Respond to recommendations provided by the location's IACUC.
- i) Support the IACUC's responsibilities relative to oversight of the location's ACUP.
- j) Cultivate an environment that values and supports prompt reporting of animal care concerns.
- k) Prepare and sign annual reports to external oversight and/or accrediting entities, as required.
- l) Assure that no individual who reports a concern will be faced with retribution or retaliation for their actions (i.e., Whistleblower Protection).

12. ARS Location IACUC Chair will:

- a) Work/consult with the IO to appoint voting members of the IACUC who are qualified to review and approve proposed research activities involving animals.
- b) Identify *ad hoc* consultants to assist the IACUC members in reviews of proposed research, when outside expertise is needed.
- c) Ensure that IACUC activities comply with all applicable regulatory requirements and policies.
- d) Prepare reports and updates to the IO for submission to ARS ONP and other external oversight and/or accrediting entities as required.
- e) Ensure the timely review of research projects involving animals that affords an opportunity for all committee members to participate.
- f) Convene IACUC meetings as often as needed to ensure the committee meets its assigned responsibilities in a timely and efficient manner. The IACUC must meet at least twice each year, at 6-month intervals, with a quorum of voting members present in order to conduct official business. In determining meeting frequency, each committee should develop criteria to determine what types of research proposals should receive additional review and discussion at IACUC meetings and those that may be appropriately reviewed by designated IACUC members outside of a convened meeting.
- g) Ensure that the results of semi-annual program reviews and facility inspections conducted by the IACUC are communicated to the IO, with the committee's recommendations for mitigating any deficiencies that are identified.
- h) Ensure bylaws and/or standard operating procedures (SOPs) and/or local policies clearly state the authority of the AV to oversee all aspects of animal well-being, including the authority to diagnose disease, prescribe treatment, and/or exercise professional discretion to remove an animal from a study (or euthanize that animal if conditions warrant).
- i) Promptly lead or delegate an investigation for any concerns and/or allegations of non-compliance that are reported. Review and report results of these investigations, including any required corrective actions, to the location's IO and to other ARS officials and/or external oversight entities, as required.

- j) Collect information and/or data that are needed to respond to public inquiries related to the location's ACUP, and provide this information to the ARS Information Staff for review and guidance on how to respond to the request.
- k) Promote constructive oversight strategies that balance quality animal care with successful research outcomes.

13. ARS Location IACUC Administrator/Coordinator/Secretary will:

- a) Send out IACUC meeting notices, draft minutes, and meeting agendas to IACUC members in a timely manner.
- b) Record minutes at IACUC meetings.
- c) Prepare other documents and reports related to the ACUP at the IACUC Chair's request.
- d) Assist the IACUC Chair in coordinating review activities for research proposals involving animals.
- e) Maintain copies and adequate records for research that has been approved by the IACUC for a minimum of 3 years after the study has been completed.
- f) Assist the IACUC Chair in coordinating semi-annual program reviews and facility inspections.
- g) Upon request, assist in maintaining and tracking training records for location staff who care for or work with animals.

14. ARS Local IACUC will:

- a) Review and approve all ARS research activities involving animals, regardless of source of funds, and ensure compliance with applicable regulations and Agency policies.
- b) Work with the corresponding researcher during the review process to ensure that the resulting protocol (1) does not unnecessarily duplicate previous research; (2) includes a justification for the use of live animals, requested species, and proposed animal numbers; (3) minimizes the level of pain/distress that research animals will experience; (4) includes veterinary consultation during protocol development when the level of pain/distress is more than momentary or exceeds minimal levels; and/or (5) includes a search for alternative methods to the use of live animals when painful/distressful procedures are proposed and scientifically justified.
- c) Conduct annual reviews of research that is in progress, and triennial *de novo* reviews of research that will be continued for more than 3 consecutive years.
- d) Monitor research that is in progress to ensure compliance with the conditions of approval.
- e) Perform semi-annual program reviews of the ACUP and inspections of animal facilities and procedure areas on a semi-annual basis, and provide the results of these reviews and recommendations for actions needed to correct any deficiencies that are identified to the IO.
- f) Promptly investigate all concerns related to animal care and use, implement any corrective actions needed to address deficiencies that are identified, and report any noncompliance(s) and/or ACUP deficiencies to the IO and external authorities, as required.

- g) Maintain appropriate documentation and records that document the IACUC's review, approval, and oversight functions and responsibilities.
- h) Establish local training and competency requirements for all individuals who are authorized to provide care or work with animals at the location.
- i) When an externally administered IACUC is used *in lieu* of establishing an ARS IACUC, the ARS location must adhere to University requirements and policies and ensure that use of the external committee is clearly documented in a formal written agreement. ARS membership or representation on the external committee should be requested if the level of support warrants ARS participation.

15. ARS AV will:

- a) Establish an adequate program of veterinary care that (1) manages the health and well-being of various populations of animals that are used for production, research, testing, and/or teaching at ARS locations and ARS study sites, and (2) evaluates the condition of their physical environments (e.g., enclosures, facilities, pastures, range, etc.), husbandry practices, and potential biosecurity concerns. A written program of veterinary care (PVC) must be developed and approved by the IACUC if the AV is not an ARS employee.
- b) Use professional judgment to assess behavioral indicators of distress of research animals maintained in production settings, and to implement appropriate strategies that will minimize potential pain and/or distress as warranted.
- c) Maintain full authority to treat or euthanize any animal for humane reasons, if such actions are judged necessary for the welfare of the animal, even if the researcher does not concur or the animal is being actively used in research, testing, and/or teaching.
- d) Serve as a subject matter expert, and provide guidance and training to scientific and support staff on all aspects of humane handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia of research animals.
- e) Serve as a resource to scientific staff relative to housing, enrichment, exercise, and other species-specific requirements.
- f) Consult with responsible researchers and jointly determine the best options for treatment of diseased animals and/or other control measures whenever an animal health or welfare concern is identified.
- g) Exercise final authority in matters related to the humane disposition of animals that are experiencing pain or distress that exceeds predetermined experimental endpoints and cannot be alleviated otherwise.
- h) Serve as a voting member of the IACUC.
- i) Provide professional input and guidance to assist the IACUC's efforts during the investigation and resolution of animal care concerns.
- j) Exercise professional judgment as an IACUC member, in order to balance animal welfare considerations with scientific objectives and facilitate a constructive research environment.

- k) Avoid potential conflicts, such as concurrently serving as a researcher and the AV with authority for treating and/or handling animal care concerns on the corresponding protocol.

16. ARS Research Leader will:

- a) Maintain a working knowledge of regulations and local policies that are relevant to animal care and use.
- b) Plan research activities in the context of a quality ACUP, and provide a sound scientific justification whenever proposed research activities deviate from relevant regulations and ARS policies.
- c) Ensure IACUC approval requirements have been met prior to initiating research activities and/or prior to implementing modifications, amendments, or other changes to approved research that involves animals.
- d) Complete required training and occupational health requirements specified by local policies, prior to commencing work with animals.
- e) Ensure all staff associated with research that involves animals are properly trained and competent to perform the duties to which they are assigned.
- f) Hold subordinate staff accountable for implementation and compliance with the Agency, Area, and location policies relevant to research involving animals and ensure mechanisms are in place to hold all location employees accountable for their ACUP responsibilities, including adoption of objective methods for monitoring the performance of these responsibilities.
- g) Support semi-annual assessments of animal facilities and written programs associated with the ACUP to ensure compliance with relevant regulations and ARS policies.
- h) Cooperate with the AV and IACUC to investigate and resolve animal care concerns that are identified.
- i) Ensure the management unit has adequate funding available to support the IACUC program, training, and animal program operations.
- j) Work to enhance the quality of animal care and use, including volunteering to serve or nominating qualified employees to serve as an IACUC member when needed.

17. ARS Principal Investigators/Lead Researchers/Scientists will:

- a) Maintain a working knowledge of regulations and local policies that are relevant to animal care and use.
- b) Plan research activities in the context of a quality ACUP, and provide a sound scientific justification whenever proposed research activities deviate from relevant regulations and ARS policies.
- c) Ensure IACUC approval requirements have been met prior to initiating research activities and/or prior to implementing modifications, amendments, or other changes to approved research that involves animals.

- d) Complete required training and occupational health requirements specified by local policies, prior to commencing work with animals.
- e) Supervise the performance of laboratory staff to ensure that appropriate procedures are followed when working with animals; immediately correct any deviations that may compromise the safety or welfare of animals used in research.
- f) Support semi-annual assessments of animal facilities and written programs associated with the ACUP to ensure compliance with relevant regulations and ARS policies.
- g) Support the IACUC's efforts to monitor compliance of approved research activities.
- h) Inform the IACUC of any concerns, complaints, and/or adverse events relevant to the care or treatment of animals used in research, and cooperate in the investigation and resolution of any deficiencies that are identified.
- i) Work to enhance the quality of animal care and use, including volunteering to serve as an IACUC member when needed.

18. ARS Research Staff/Support Scientists/Technicians will:

- a) Complete training requirements and occupational health requirements specified by local policies, prior to commencing research duties.
- b) Read and understand the approved protocol for every study to which they are assigned to support.
- c) Regularly observe all animals within their assigned areas of responsibility, and assist the Principal Investigator and AV in monitoring their health and welfare.
- d) Ensure animal observations, experimental manipulations, and other procedures are accurately documented.
- e) Report any animal welfare concerns related to a particular study or general animal care to the scientist responsible for the study, the AV, an appropriate supervisor, or a member of the IACUC; reports can be submitted verbally, in writing, and/or anonymously, but must be submitted as soon as the concern is identified. Individuals should initially communicate concerns directly to their local authorities, but also have the discretion to report these issues to higher management, the ARS Ombudsman, and/or ARS Animal Care and Use Officer. No individual who reports a concern will be faced with retribution or retaliation for their actions.

19. ARS Support Staff/Animal Caretakers/Facility Maintenance Staff will:

- a) Regularly observe all animals within their assigned areas of responsibility, and assist the AV in monitoring their health and welfare.
- b) When requested, complete training to be able to provide appropriate care for species at the location and to assist in vaccination, deworming, treatment, and/or diagnostic sample collection from these animals.
- c) When requested, complete training to assist research staff in performing various procedures, data collection, and/or monitoring animals for potential research complications.

- d) Ensure animal observations and any procedures that are performed are accurately documented.
- e) Work collaboratively with the IACUC to ensure animal facilities and environments are appropriate for the species that are maintained and in good repair.
- f) Respond promptly to emergency situations that have the potential to compromise animal health and/or welfare.
- g) Report any concerns related to animal care to the AV, an appropriate supervisor, or a member of the IACUC; reports can be submitted verbally, in writing, and/or anonymously, but must be submitted as soon as the concern is identified. Individuals should initially communicate concerns directly to their local authorities, but also have the discretion to report these issues to higher management, the ARS Ombudsman, and/or ARS Animal Care and Use Officer. No individual who reports a concern will be faced with retribution or retaliation for their actions.

20. IACUC Roles and Responsibilities:

Training

- a) Individuals who serve on the IACUC must be properly trained to fulfill their committee responsibilities.
- b) At minimum, training must be provided in humane methods of animal maintenance and experimentation; limiting pain and/or distress experienced by animals used in research activities; proper use of anesthetics, analgesics, and tranquilizers; deficiency reporting; searching for alternatives to the use of live animals in research; and prevention of unnecessarily duplicative research.
- c) Activities that qualify for credit as training include completion of approved online courses; attending ARS animal care and use webinars; review of IACUC-selected continuing education articles in approved journals; attending an IACUC- or animal use-related regional or national conference; and individual training that is provided by local subject matter expert in animal care and use.

Convening Meetings

- a) A quorum of members must be present in order for official business to be conducted. Members can participate by attending the meeting in person, by telephone, through videoconference, or other web-based methods that permit members to interact in real time. It is not acceptable for meetings to be conducted through email exchange or other methods of communication that do not provide opportunities for live discussion.
- b) The IACUC should meet at regular intervals, and at a frequency that conforms to the research program's needs, but no less than twice each year (i.e., every 6 months).
- c) The Chair has the option to convene an emergency meeting when urgent issues arise.

Reviewing and Approving Research Activities that Involve Animals

- a) The IACUC must review and approve all research involving live animals prior to initiation. All IACUC members must be provided with a list of proposed protocols prior to review.
- b) The committee has the option to conduct reviews during a convened meeting of a quorum of members (i.e., full committee review or FCR) or to delegate review and approval authority to one or two designated members acting on the committee's behalf (designated member review or DMR).
- c) DMR cannot be used unless all committee members have been given the opportunity to review the submission and concur that the use of DMR is appropriate. FCR can be requested by any member at any time, and must be used *in lieu* of DMR if requested.
- d) In addition, DMR can be used subsequent to FCR when modifications are needed to secure approval. In these situations, the members in attendance can authorize the use of DMR by unanimous vote if all members have agreed to this practice in advance.
- e) At minimum, the review process must include (1) an assurance that the research does not unnecessarily duplicate previous research; (2) criteria for species selection and specifically why lower order vertebrates cannot be used; (3) a justification for the number of animals requested; (4) a rationale for the use of live animals *in lieu* of available *in vitro* alternatives; (5) strategies to minimize pain and distress; (6) establishment of humane endpoints; and (7) an animal disposition or euthanasia plan.
- f) Deviations from standards articulated in the AWAR, *Ag Guide*, or *CCAC Guidelines* must be scientifically justified in the protocol and approved by the IACUC.
- g) The review process has three possible outcomes that include: (1) the protocol is approved as submitted; (2) the protocol needs modifications to secure approval; or (3) approval is withheld.
- h) Modifications to an approved protocol must also be reviewed and approved by the IACUC prior to implementation.
- i) In accordance with the AWAR, ongoing protocols involving regulated species must be reviewed no less than once each year. The ARS P&P extends this requirement to all species.
- j) A triennial *de novo* review of every protocol involving live animals must be completed at least every 3 years following initial approval. In order for research to continue, an updated protocol must be submitted and approved prior to the third year anniversary.
- k) The IACUC must ensure that the principles of reduction, refinement, and/or replacement (the 3 R's) are incorporated into all phases of research planning and conduct.

Conducting Semi-Annual Program Reviews and Facility Inspections

- a) The IACUC must (1) evaluate the institution's ACUP, and (2) inspect areas where animals are held, transported, housed, maintained, and/or used in research activities at least once every 6 months.

- b) A minimum of two members must actively participate in the inspection process, although all members are encouraged to contribute and should be involved to the greatest extent possible.
- c) The IACUC has the option to consult with external subject matter experts during its evaluation of unusual species and/or alternate environments required for certain studies.
- d) The results of this self-assessment are compiled into a final report that identifies the program's departures from regulations or recognized performance standards, with an explanation or reason for each departure.
- e) The report must also classify deficiencies as "minor" (i.e., do not present an immediate threat to the health and welfare of research animals or facility personnel) or as "significant" (i.e., pose an immediate threat to the health and welfare animals or facility personnel). A reasonable and specific plan and schedule for resolution of each deficiency must be included with the report. Development of the plan should be in consultation with affected managers, administrators, and/or research staff to ensure the resulting proposal can be successfully implemented.
- f) The report must also incorporate the IACUC's recommendations to the IO relative to the ACUP, facilities, and/or personnel training.
- g) The final report must be reviewed and approved by the IACUC, and then signed by a majority of the members. Any minority opinions that are expressed must be included. The IACUC is responsible for the content of the report, and no other individual or entity has the authority to alter the document after it has been approved and signed.
- h) IACUC representatives must present the results of the final report to the IO in person during a live meeting or through a teleconference that provides an opportunity for discussion of complex issues. The IO must sign the final report as acknowledgement of its receipt.
- i) The institution must report any failure to adhere to the proposed corrective action plan for significant deficiencies to APHIS, the Animal Care and Use Officer, and any other Federal agency(ies) through which funding is received. The report must be submitted within 15 business days of the lapse.
- j) The IACUC's semi-annual program review and facility inspection report is intended to document the institution's overall compliance with relevant regulations and ARS policies. As such, it is a critical function and essential in maintaining the integrity and effectiveness of the institution's local oversight of research activities involving live animals.

Establishing Local Policies Relevant to Animal Care and Use

- a) The IACUC has responsibility for implementing local policies as needed to adhere to the Agency P&P and to address regulatory requirements and responsibilities using scientifically sound, performance-based standards.

- b) The IACUC must ensure these policies are clearly articulated to scientists, research personnel, and support staff through the establishment of effective training programs and that mechanisms are in place to monitor local compliance.
- c) Examples of policies that are highly recommended and should be established at every ARS location include: (1) procedures for reporting animal care concerns; (2) training and assessing competency of staff who work with animals; (3) occupational health programs for staff who work with animals; (4) plans to minimize animal harm and distress during disaster situations; and (5) procedures to monitor approved research activities for compliance (i.e., post-approval monitoring). This is not an inclusive list, and each location may develop policies to address their program's specific needs.

Investigating and Resolving Animal Care Concerns

- a) A local policy must be developed to provide guidance and procedures for identifying, reporting, and investigating concerns related to animal care and use.
- b) Concerns may be submitted by facility personnel or the public, and there should be a mechanism that allows multiple individuals within the organization to receive the reports, including supervisors, the AV, IACUC Chair or members, and/or the IO. Whenever possible, the IACUC Chair will acknowledge that a concern has been received.
- c) There should be provisions to ensure those who report concerns are protected, and will not be subject to retributions or reprisals for their actions.
- d) Within reason, the confidentiality of those who report will be protected, although the source of the concern may be disclosed accidentally or intentionally during the subsequent investigation.
- e) Individuals may also submit anonymous reports, which will be investigated to the fullest extent possible. The IACUC will act as "complainant" for anonymous concerns.
- f) The procedure should include options for timely suspension of research activities that are not in compliance or that significantly jeopardize the health and welfare of the animals or research workers.
- g) The final determination of the IACUC's investigation and any associated corrective actions will be documented and communicated to the IO by IACUC representatives.

Maintaining ACUP Documentation and Records

The IACUC must ensure the following records are maintained and available for review:

- a) Current committee rosters and letters of appointment for individuals who are serving on the local IACUC;
- b) IACUC meeting minutes covering at least the previous 3 years of business, although locations have the discretion to retain these records for longer periods of time if warranted;

- c) Protocol records and files, including expired or closed protocols for a minimum of 3 years after protocol expiration or study completion;
- d) Semi-annual program review and facility inspection reports, with recommendations, covering the previous 3 years at minimum;
- e) Records that document satisfactory resolution of program and facility deficiencies, including minutes, tracking spreadsheets, work orders, emails, etc. covering the previous 3 years at minimum;
- f) Current local policies and procedures relevant to the ACUP;
- g) Training records for IACUC members, research personnel, animal care staff, and others who care or work with animals covering the previous 3 years at minimum; and
- h) Records of communications, routine reports, and notices of program deficiencies that have been submitted to external oversight authorities, such as ONP, APHIS, the National Institutes of Health – Office of Laboratory Animal Welfare (NIH-OLAW), and the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) over the previous 3 years at minimum.
- i) To protect the privacy of individuals serving on the IACUC, the names of members (other than the Chair and AV) can be represented as initials, numbers, or other symbols in the minutes and other official program records that may be requested through the Freedom of Information Act (FOIA).

Externally Administered IACUC:

- a) ARS locations have the option to enter into a formal agreement to use a partner institution's IACUC for the oversight of ARS research involving live animals *in lieu* of establishing an ARS IACUC.
- b) The agreement to obtain the services of an externally administered IACUC must be documented in writing and signed by an individual authorized to represent the interests of each participating institution.
- c) The agreement should include an assurance that the externally administered IACUC will adhere to animal care and use standards that are equivalent to those described in this P&P, and that ARS animal research will be conducted in an environment where proper facilities, professional staffing, and adequate administrative support are available.
- d) When an externally administered IACUC is used, affected ARS researchers must adhere to the partner institution's internal policies and requirements pertaining to animal research activities and training.
- e) A *de facto* ARS IO should be appointed to serve as a liaison and coordinate interactions between the two institutions.

- f) ARS membership or representation on the external committee should be requested if the level of support warrants formal ARS participation.

Authorities

1. [AAALAC Rules of Accreditation](#)
2. [ACLAM Position Statement on Adequate Veterinary Care](#)
3. [USDA Animal Welfare Inspection Guide](#)
4. [Animal Welfare Act \(AWA\)](#)
5. [Animal Welfare Act Regulations](#)
6. [APHIS Animal Care Policies](#)
7. [Guide for the Care and Use of Agricultural Animals in Research and Teaching](#)
8. [AVMA Guidelines for the Euthanasia of Animals](#)
9. [Canadian Council on Animal Care Guidelines on the Care and Use of Fish in Research, Teaching, and Testing](#)
10. [Guide for the Care and Use of Laboratory Animals](#)
11. [PHS Policy on Humane Care and Use of Laboratory Animals](#)
12. [U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)

Definitions

1. Accreditation: Refers to a voluntary independent third party verification of an institution's animal care and use program by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC); the accreditation process promotes the humane and ethical treatment of animals in science and ensures that an institution adheres to the highest standards of animal care and use.
2. Alternatives (or Alternative Methods): Any system or method that covers one or more of the following: (1) replacing the use of laboratory animals altogether; (2) reducing the number of animals required; or (3) refining an existing procedure or technique to minimize the level of

pain/distress perceived by the animal (also known as “the 3 R’s” for replacement, reduction, and refinement).

3. Analgesia: A neurologic or pharmacologic state in which painful stimuli are moderated and no longer painful (i.e., absence of sensibility to pain) without a complete loss of consciousness.
4. Anesthesia: Agents that block sensation and/or interfere with the passage of pain impulses along nerve pathways to the brain following administration; these agents may produce localized effects or result in temporary loss of consciousness.
5. Animal: A living vertebrate species, other than humans. In ARS, the term includes animals used for research, teaching, or testing; those that are maintained exclusively for food and fiber production that is independent of research; and those that are maintained to protect or assist in the management of other animals (i.e., herding dogs, horses, burros, llamas, etc.). Invertebrates, eggs, embryos, and/or fertile eggs or larvae that have not developed beyond exclusive reliance on their own yolk nutrients are not included in the definition of animal.
6. Animal Care and Use Program (ACUP): An ACUP includes all activities that are conducted by and at an institution which have a direct impact on the well-being of animals, including the program of animal and veterinary care; institutional policies and procedures; personnel and program management and oversight; occupational health and safety for individuals that work with animals; IACUC functions; and animal facility design and management.
7. Animal Research: Scientific investigations or activities that are dependent on the use of vertebrate animals for the generation of data. This includes studies that involve manipulation of animals; collection of samples from live animals or from animals that have been euthanized specifically for the purpose of tissue harvest; and/or noninvasive observational or behavioral studies. Studies that are dependent on the influence or effects of animals for non-animal data collection (i.e., grazing studies, habitat studies, etc.) are only considered to be animal research when data is collected from the animals or when the research alters animal behavior. Grazing studies that focus exclusively on the environment (i.e., soil, pasture, crop, run-off, etc.) and do not involve collection of any animal data (i.e., body weights, food consumption, etc.) are not considered animal research and exempted from full IACUC review. Provisions must be in place to ensure all animals receive adequate care and oversight even when a study is not classified as animal research.
8. ARS Research: A research project that is conducted: (1) with ARS funding; (2) at an ARS facility/location, with oversight provided by an ARS IACUC; (3) with ARS resources, in this case animals that are owned or leased by ARS; and/or (4) under the direction of an ARS-salaried scientist while on official time.

9. APHIS Animal Care: The administrative unit in USDA Animal and Plant Health Inspection Service (APHIS) that is charged with enforcing the Animal Welfare Act Regulations and Standards.
10. Animal Welfare Act: Public Law 89-544. Title 7 of the U.S. Code (7 USC) §§2131 et. Seq. The law that, in part, is intended to ensure that animals used in research facilities (as defined therein) are provided humane care and treatment.
11. Animal Welfare Act Regulations: Detailed regulations and standards for implementing the Animal Welfare Act, found in Title 9 of the Code of Federal Regulations (9 CFR), Chapter 1, Subchapter A, Parts 1, 2, and 3.
12. Association for the Assessment and Accreditation of Laboratory Animal Care, International: A private, nonprofit organization that promotes the humane and ethical treatment of animals used in science through voluntary accreditation and assessment programs; AAALAC works through institutions and researchers to serve as a bridge between scientific progress and animal well-being; accreditation through AAALAC is regarded as the international gold standard for excellence in the care and use of laboratory animals.
13. Attending Veterinarian (AV): The veterinarian who has been given direct or delegated authority for the ACUP at an ARS location, and is appropriately trained, experienced, and credentialed to assume these duties; licensing is optional, but may be a requirement for some positions. The AV may be employed by ARS or provide these services as an outside consultant.
14. De Facto: A Latin expression that means “in fact, in reality, in actual existence, in force, in possession, or as a matter of fact;” it is applied to a practice that is followed for practical purposes, although not officially established or ordained by law. An Institutional Official (IO) is recognized by external regulatory authorities as having full legal jurisdiction over an animal care and use program, whereas a *de facto* IO has been informally given limited authority for a specific component (i.e., ARS research activities only).
15. Designated Member Review (DMR): One of the two valid methods of IACUC review and approval that involves one or two voting members conducting a review on the full committee’s behalf, after all voting members have been provided with an opportunity to request that these actions be performed at a convened meeting and unanimously agree to the use of DMR instead.
16. Externally Administered IACUC: An IACUC that is administered by an entity other than the ARS location that is performing research with animals (i.e., University, alternate ARS location, non-ARS research entity, etc.), and serves as the IACUC of record for that location.

17. Euthanasia: The use of humane techniques to end the life of an animal in a way that minimizes or eliminates pain and distress to the greatest extent possible; acceptable methods and conditions for their use are described in the most recent version of the *American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals (AVMA Guidelines)*.
18. Full Committee Review (FCR): One of the two valid methods of IACUC review and approval, which involves a quorum of voting members conducting the review during a convened meeting.
19. Institutional Animal Care and Use Committee (IACUC): The local committee qualified through the experience and expertise of its members that oversees its institution's animal program, facilities, and animal procedures; the IACUC is charged with ensuring compliance with animal research regulations, guidelines, and ARS policies.
20. Institutional Official (IO): The individual at each ARS location who has been delegated responsibility for local research activities involving animals, and who has the legal authority to commit personnel, resources, and institutional priorities to ensure the program adheres to relevant Agency policies and standards concerning the care and use of animals; the IO is typically the chief administrator for an ARS location, such as a Center Director, Laboratory Director, Location Coordinator (when an ARS location has multiple laboratories), or other Senior Program Official.
21. Minority Opinion: A belief or judgment based on evidence insufficient to produce complete certainty and which represents the view of an individual or the smaller part of a group (less than one-half of the members and sometimes a single individual).
22. NIH Office of Laboratory Animal Welfare (OLAW): NIH-OLAW provides guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, supports educational programs, and monitors compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities.
23. Nonaffiliated Member: An IACUC member, whose only ties to ARS are through his or her service as an IACUC member and can provide perspectives that are unique to the public or local community; individuals who have family members that are employed by ARS or that work for a business that provides services to an ARS location are not eligible to serve as a nonaffiliated member.
24. Nonscientist Member: An IACUC member, whose primary concerns are in a nonscientific and nontechnical field, and can provide the perspectives of a lay person; individuals who may

qualify include members of the clergy, librarians, attorneys, accountants, teachers, ethicists, local business owners, etc.

25. Public Health Service (PHS): The U.S. Public Health Service, which is part of the U.S. Department of Health and Human Services that includes the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC).
26. PHS Policy: *Public Health Service Policy on Humane Care and Use of Laboratory Animals*. This policy implements the Health Research Extension Act, and must be followed by institutions that are awarded PHS funding.
27. Principal Investigator (PI): Employees or other individuals formally associated with an ARS research facility, who are directly responsible for the design, implementation, and/or conduct of research involving animals; a PI may also be referred to as Lead Researcher or Scientist (SY).
28. Protocol: A written document or completed form that provides a detailed description of how animals will be used to answer specific research objectives in a defined project, and that is submitted to the IACUC to obtain approval for these activities.
29. Quorum: A simple majority (half the membership plus one); the minimum number of members that must be present at any convened meeting in order to conduct official business and make the proceedings of that meeting valid.
30. Reduction: Procedures or measures taken to reduce the total number of animals used, without negatively impacting the statistical validity of the results. Reduction may include optimizing a study to utilize animals as their own controls; gathering a maximum amount of data from each animal subject (e.g., by gathering data for more than one experiment concurrently, or designing experiments to prevent the need for duplicate control groups); and using more sophisticated measuring techniques to improve precision and reduce the sizes of the groups that are needed.
31. Refinement: Procedures or measures taken to eliminate or minimize pain and distress, or to otherwise enhance the well-being, of animals used in research. Refinement may include identifying ways to prevent or relieve pain/distress likely to be caused by experimental procedures; setting the earliest possible endpoints for the research; using more appropriate analgesics and anesthetics for potentially painful procedures as they become available; and increasing the effectiveness of post-procedural care with new technologies and palliative therapies.
32. Regulated Species: Animals covered under the Animal Welfare Act, which includes live, warm-blooded vertebrate species used in teaching, testing, experiments, or research protocols

except for aquatic species, birds, rats of the genus *Rattus* that are specifically bred for research, mice of the genus *Mus* that are specifically bred for research, and agricultural species that are used exclusively for food and fiber (i.e., agricultural) research activities.

33. Replacement: Procedures or measures that eliminate the need for animals in research activities, and usually refers to the use of *in vitro* techniques or computer simulations in place of procedures that involve animals. Sometimes the term is also applied when less sentient species (i.e., invertebrates, reptiles, amphibians, etc.) are used in place of more sentient species such as mammals.
34. Research Animal: Live vertebrates used, or intended for use, in teaching, testing, and research for agricultural and/or biomedical purposes, including rodents, avians, and aquatic species. The scope of this definition includes animals used for: (1) biomedical research; (2) public health research; (3) projects that focus on agricultural animal husbandry, production, physiology, and health; and (4) other agricultural-based research activities where animals are essential for the collection of data, such as observational, behavioral, environmental, and foraging studies. Animals that are essential to non-animal research outcomes, but are not manipulated or otherwise used for data collection (i.e., ruminant species used for grazing studies to assess environmental impact, pest populations, etc.) are not considered “research animals.” Likewise, animals that are not essential to research, but which are maintained to protect and/or assist in the management of research flocks and herds (i.e., herding dogs, burros, llamas, etc.) are not considered “research animals.” The ACUP must include provisions for the oversight of all animals, both research and non-research, to ensure they receive an appropriate level of care.
35. Research Leader (RL): The leader for a group of scientists engaged in a specific area of research, and who helps to plan and oversee various research initiatives undertaken by that group; the RL is also an active researcher.
36. Research Staff or Personnel: Individuals who assist scientists in the performance of skilled research activities, including experimental procedures, special observations, collection of data, and other specialized animal care that may be required while an experiment is in progress; research staff may be employed by ARS or a collaborator.
37. Senior Management Official: The individual who is assigned to the highest ranking management or supervisory position at an ARS location and who has overarching responsibility and authority for the staff, resources, and/or funding needed to support that location’s ACUP or to enter into an agreement with another institution to secure the necessary services. A Center Director, Laboratory Director, Location Coordinator (when an ARS location has multiple laboratories), Research Leader, or other Senior Program Official may be designated as the ARS Senior Management Official. Each ARS location must make the determination regarding who meets this definition.

38. Significant Deficiency: A deficiency, which in the judgment of the IACUC and IO, is or may be a serious and immediate threat to the health or safety of animals.
39. Support Staff or Personnel: Individuals responsible for routine animal care and/or facilities maintenance and repairs; these individuals provide basic husbandry services and maintain a healthy living environment for the animals at various ARS locations, and may be employed by ARS or a collaborator.
Routine animal care includes daily observations; facility and equipment sanitation; provision of food and water; animal transportation; weighing animals; milking; egg collection; etc.
Environmental maintenance and repairs includes facility and fence construction or repairs; maintenance and repair of facility infrastructure (i.e., heating, ventilation, and air conditioning systems, plumbing, electrical systems, etc.); pasture upkeep; pest management services; etc.
40. Training: A requirement of the AWAR and PHS Policy, which states that all personnel participating in the use of animals under an IACUC-approved protocol must receive appropriate training in humane methods of animal maintenance and experimentation; methods to limit the level of pain and/or distress experienced by animals used in research activities; proper use of anesthetics, analgesics, and tranquilizers; reporting of animal care concerns and program deficiencies; and accessing databases and online services that prevent unnecessary duplication of research and/or provide information on alternatives to the use of live animals in research activities.
41. Triennial *De Novo* Review: An in-depth continuing review of research activities that involve animals, which is performed by the IACUC every 3-years and uses the same assessment criteria that is used for a new protocol submission (PHS Policy IV.C.5).

Approved by:

/srs/
Steven R. Shafer
Associate Administrator
Office of National Programs

02/05/2016
Date